K122834

PEROUSE MEDICAL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
As required by section 807.92(c)

DEC 11 2013

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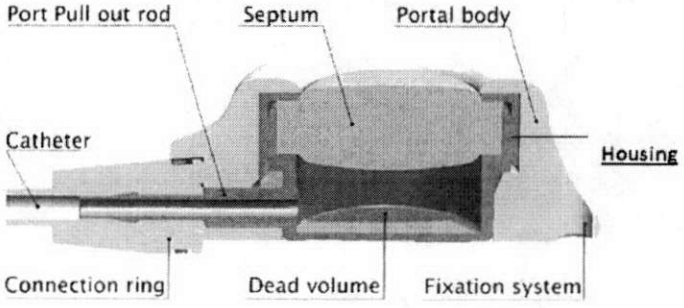
Contacts	Isabelle JEANTY Deputy Managing Director - Quality & Regulatory Affairs Director e-mail : i.jeanty@perousemedical.com
Preparation date	April 12th 2013
K number	K122834
Trade Name	POLYSITE® Implantable Infusion Port (CATALOG REFERENCES: 2016PI – 3017PI– 4018PI – 2016SPI – 3017SPI – 4018SPI- 2016C -3017C - 4018C – 2016SC – 3017SC – 4018SC)
Common Name	Implantable Infusion Port
Classification Name	PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVASCULAR
Legally marketed predicate devices	- PowerPort isp Implantable Port with attachable 8Fr. Chronoflex Polyurethane Catheter (K072215) - Slimport Titanium implantable port with attachable 6F Chronoflex Open-ended single-lumen venous catheter (K870260)
Description	POLYSITE Implantable Infusion Port is composed of a radiopaque dome or housing and a self sealing septum, connected to a radiopaque catheter by a connecting ring (supplied unassembled). The port is accessed percutaneously by using a non-coring needle. 

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SIREN 317 883 999 RCS Beauvais
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Technological characteristics	Technological characteristics of the subject devices are equivalent to predicated devices. This equivalence extends to basic design generic materials and construction. The distinguishing differences exists in: - the external portal body material: titanium for the predicates, and plastic for the subject devices - the markers of POLYSITE Pressure Injectable are visible under X-ray and visible light, the marking of the predicate is only visible under X-ray. The symbol used is also different. These differences do not impact the intended use and do not raise any new questions regarding safety or effectiveness.
Intended Use	The POLYSITE implantable infusion Port is indicated for long term access to the central venous system and allows for repeated vascular access. POLYSITE Implantable Infusion venous access ports are used to administer chemotherapy, antibiotics and antiviral drugs. They can also be used for parenteral nutrition, collection of blood samples and transfusion of blood or blood products. A non-coring needle must be used to access POLYSITE Implantable Infusion Ports. Some references of POLYSITE (POLYSITE Pressure Injectable Implantable Infusion Port-PI references) can be used for high pressure injection of contrast media during diagnostic studies. The maximum flow rate of power injector equipment used with the pressure injectable port may not exceed 5 mL/s. For high pressure injection of contrast media, a high pressure needle must be used to access the POLYSITE Pressure Injectable implantable infusion port. The manufacturer recommends the use of PPS PI Pressure Injectable Safety Huber needle.
Performance data	Performance data included with this submission - Biocompatibility according to ISO 10993-1: 2009 - Safety and functionality testing o in accordance with the FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports" dated October 1990: - Catheter to port connection (dry and wet conditions) - Septum puncture (with 19, 20 and 22 Gauge needles) - Port leak testing (air method) - Clearance (fluids dynamic test)

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	o Other: - Radioopacity determination - Evaluation of magnetic field interactions, heating and artifacts at 3 Tesla - High pressure injection simulation - Static burst test - Contrast media injection limits - Catheter tensile strength - Maximum flow rate - Absence of septum leak after 19 Gauge needle punctures - Coring absence
Clinical data	Clinical studies were not deemed necessary since the intended use and the technological characteristics are substantially equivalent to others marketed ports. Satisfactory in vitro testing and adequate instructions for use are sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.
Substantial equivalence	POLYSITE Implantable Infusion Ports are substantially equivalent to their predicate devices in term of intended use and technological characteristics (materials, design and functionality).
Conclusion	Performance data demonstrate safety, effectiveness and substantial equivalence

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2013

Perouse Medical
Ms. Isabelle Jeanty
Deputy Managing Director – Quality & Regulatory Affairs Director
Route du Manoir
60173 Ivry Le Temple
FRANCE

Re: K122834
Trade/Device Name: POLYSITE Implantable Infusion Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, OKE
Dated: December 3, 2013
Received: December 4, 2013

Dear Ms. Jeanty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. for
Ulmer -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K122834

Device Name
Polysite Implantable Infusion Port

Indications for Use *(Describe)*
The POLYSITE implantable infusion Port is indicated for long term access to the central venous system and allows for repeated vascular access.

POLYSITE Implantable Infusion venous access ports are used to administer chemotherapy, antibiotics and antiviral drugs. They can also be used for parenteral nutrition, collection of blood samples and transfusion of blood or blood products.

A non-coring needle must be used to access POLYSITE Implantable Infusion Ports.

Some references of POLYSITE (POLYSITE Pressure Injectable Implantable Infusion Port-PI references) can be used for high pressure injection of contrast media during diagnostic studies. The maximum flow rate of power injector equipment used with the pressure injectable port may not exceed 5 ml/s.

For high pressure injection of contrast media, a high pressure needle must be used to access the POLYSITE Pressure Injectable implantable Infusion port. The manufacturer recommends the use of PPS PI Pressure Injectable Safety Huber needle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.09 15:51:14 -05'00'

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